510 (K) Summary

K083288

SUMMARY OF SAFETY AND EFFECTIVENESS FOR
Discon Plus (Etafilcon A) Contact Lens visibility tint with UV blocker

SEP - 8 2009

Submitter Information:

Company:	INNOVA VISION INC.
	No. 231-1, Wen-Te Road, Chiung-lin Village, Hsin-Chu County, Taiwan.
Contact Person:	Mr. Michael w. Hsu,
	Executive Vice President
Phone:	886-3-592-7299
FAX:	886-3-592-6213
E-Mail:	mikehsu@innovavision.com.tw
Date Prepared	Sept. 20, 2008

Identification of Device:

Classification Name:	Soft hydrophilic contact lens, per 21 CFR. 886.5925
Trade Name:	Discon Plus (Etafilcon A) Contact Lens visibility tint with UV blocker
Common or usual Name:	Soft (hydrophilic) Contact lens (daily wear)
FDA Classification:	Class II

Predicate Device:

Discon (Etafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear cleared via K051129 INNOVA VISION INC. Taiwan	ACUVUE (Etafilcon A) Contact Lens clear and visibility tint with UV blocker cleared via K962804 Vistakon, USA

Indications for Use

Discon Plus (Etafilcon A) Contact Lens visibility tint with UV blocker is indicated for daily wear for the correction of refractive ametropia in not-aphakic persons with non-diseased eyes that are myopic or hyperopic and may exhibit refractive astigmatism up to 2.00 diopters that does not interfere with visual acuity.

Eye care practitioners may prescribe the lenses for either single-use daily disposable wear or frequent/planned replacement wear with cleaning, rinsing, disinfection and scheduled replacement as **prescribed by the eyecare professional.** When prescribed for frequent/planned replacement wear. The contact lens may be disinfected using chemical (not heat) disinfection system.

Description of Device

The Discon Plus (Etafilcon A) Contact Lens visibility tint with UV blocker is available as non-spherical lenses manufactured by spin-casting method. The model illuminated with high water content (58 %). The hydrogel lens' material is a random copolymer composed of 2-hydroxyethyl methacrylate (HEMA) and methacrylic acid (MAA), which was cross-linked with 1,1,1-trimethylolpropane trimethacrylate (TMPTMA) and Ethylene Glycol Dimethacrylate (EGDMA) via UV photo- polymerization. The Discon Plus (Etafilcon A) Contact Lens visibility tint with UV blocker is tinted blue using C.I Reactive blue 19 to make the lens more visible for handling In the Discon Plus Contact Lens with UV Blocker, a Benzophenone UV absorbing monomer is used to block UV radiation. The average transmittance characteristics for Discon Plus lens are less than 5% in the UVB range of 280nm - 315nm and less than 30% in the UVA range of 316nm - 380nm. Lenses are supplied sterile in sealed blister packers containing sterile isotonic phosphate buffered saline solution.

Summary of Clinical Study

This 510(k) application describes a UV absorbing compound addition to the predicate device – Discon (Etafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear cleared via K051129 INNOVA VISION INC. There is no change in the manufacturing process, nor the parameter and properties. The clinical data previously submitted in K051129 supports the clinical safety of the subject device. Besides, the UV absorbing compound and UV-blocking ability are equivalent to ACUVUE (Etafilcon A) Contact Lens clear and visibility tint with UV blocker cleared via K962804 Vistakon. Therefore, no clinical data is required for this submission.

Nonclinical Studies

All testing was conducted in accordance with the May 1994 FDA guideline titled *Premarket Notification 510(K) Guidance Document for Class IV Contact lenses.*

The non-clinical performance tests had been performed to demonstrate the safety and effectiveness of the Discon Plus (Etafilcon A) Contact Lens visibility tint with UV blocker, and establish substantial equivalence to predicate lenses-Discon Lens (K051129); ACUVUE (Etafilcon A) Contact Lens clear and visibility tint with UV blocker (K962804). The evidence of substantial equivalent to the predicate lens described as follow:

a) Technological characteristics studies

The technological characteristics of Discon Plus (Etafilcon A) Contact Lens visibility tint with UV blocker as compared to those of predicate lenses are illustrated in the following table.

Characteristic	Discon Plus	Discon (K051129)	Acuvue (K962804)
FDA group #	Group # 4 >50% Water, Ionic Polymers	Group # 4 >50% Water, Ionic Polymers	Group # 4 >50% Water, Ionic Polymers
USAN name	Etafilcon A	Etafilcon A	Etafilcon A
Production method	Spin-casting	Spin-casting	Cast-molded
%Water content	58	58	58
Refractive index	1.40	1.40	1.40
Oxygen permeability (edged corrected) @ 35℃	24×10^{-11} [(cm^2/sec)(ml O^2/ml-mmHg)]	24×10^{-11} [(cm^2/sec)(ml O^2/ml-mmHg)]	26×10^{-11} [(cm^2/sec)(ml O^2/ml-mmHg)]
Power, Diopters	+20.0D~-20.0D	+6.0D~-12.0D	+20.0D~-20.0D
%Light transmission			
%T @381~700 nm	93 minimum	93 minimum	85 minimum
%T @316~380 nm	avg <30%	NA	avg <30%
%T @280~315 nm	avg<5%	NA	avg<5%

b) Biocompatibility

The following non-clinical tests were conducted as recommended by the Premarket Notification guidance document for Daily Wear Contact Lenses, revised May 1994.

1. Toxicology testing

a. Cytotoxicity

b. USP Ocular Irritation

c. USP Systemic Injection

c) Microbiology

Steam sterilization process has been validated to deliver a minimum SAL of 10^{-6}, thereby complying with the requirement of FDA Group IV. There is shelf-life stability data supporting that the lens remains sterile through the expiration date claimed for the product.

d) Leachability

Studies were conducted to determine the leachable materials from the finished lens. The results show that, at the levels of the detection reported, there are no leachable monomers and addictive residues.

Substantial Equivalence Statement

In conclusion, it is Innova's conviction that data submitted in this 510(k) to validate the claim of substantial equivalency, substantiates our ability to manufacture a soft contact lens, the Discon Plus (Etafilcon A) Contact Lens visibility tint with UV blocker, with the same established safety profile and effectiveness as the predicate device-- Discon (Etafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear cleared via K051129 & ACUVUE (Etafilcon A) Contact Lens clear and visibility tint with UV blocker cleared via K962804.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

MAR 23 2010

Innova Vision, Inc.
c/o Harvest Consulting Corp.
Ms. Jennifer Reich
Senior Consultant
2904 N. Boldt Drive
Flagstaff, AZ 86001

Re: K083288
Trade/Device Name: Discon Plus (etafilcon A) Contact Lens visibility tint with UV blocker
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) Contact Lens
Regulatory Class: II
Product Code: LPL, MVN
Dated: August 12, 2009
Received: August 18, 2009

Dear Ms. Reich:

This letter corrects our substantially equivalent letter of September 3, 2009.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

INDICATIONS FOR USE STATEMENT

510(k) Number: K083288

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Indications for Use:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devices

510(k) Number K083288

Prescription Use: ☑ or Over the Counter Use ☐

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(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K083288